We claim:

1. Highly pure cefditoren pivoxil, wherein the cefditoren pivoxil has a purity greater than 98.5% and contains less than 1.0% of E-isomer impurity and less than 1% of Δ^2-isomer impurity.

2. The compound according to claim 1, wherein the compound is in an amorphous form.

3. The compound according to claim 2, wherein the compound has a XRD pattern as depicted in Figure I.

4. The compound according to claim 1, wherein the compound is in a crystalline form.

5. The compound of claim 4, wherein the compound has a XRD pattern as depicted in Figure II.

6. A process for preparing crystalline cefditoren pivoxil from amorphous cefditoren pivoxil, the process comprising:

   a) (i) adding amorphous cefditoren pivoxil to an organic solvent optionally containing water and/or (ii) adding an organic solvent optionally containing water to amorphous cefditoren pivoxil;

   b) crystallizing the product from the reaction mixture; and

   c) isolating crystalline cefditoren pivoxil.

7. The process according to claim 6, wherein the organic solvent is one or more of an alcohol, a ketone, an ester, a cyclic ether, a nitrile, a glycol, a chlorinated hydrocarbon, or a mixture thereof.

8. The process according to claim 7, wherein the alcohol is one or more of ethanol, methanol, isopropyl alcohol, n-butanol, iso-butanol, amyl alcohol or a mixture thereof.

9. The process according to claim 7, wherein the ester is one or more of ethyl formate, methyl acetate, ethyl acetate, isobutyl acetate, butyl acetate or a mixture thereof.

10. The process according to claim 7, wherein the ketone is one or more of acetone, methyl ethyl ketone, diisobutyl ketone, methyl isobutyl ketone or a mixture thereof.

11. The process according to claim 7, wherein the cyclic ether is one or more of tetrahydrofuran, 1,4-dioxane or a mixture thereof.

12. The process according to claim 7, wherein the glycol is one or more of propylene glycol, ethylene glycol or a mixture thereof.

13. The process according to claim 7, wherein the chlorinated hydrocarbon is one or more of methylene chloride, ethylene chloride, chloroform or a mixture thereof.

14. The process according to claim 7, wherein the organic solvent contains about 0.01 to about 50% by weight of water.

15. The process according to claim 6, wherein the reaction mixture is stirred at a temperature of about –20°C to about 100°C to crystallize.

16. The process according to claim 6, wherein the crystallization temperature is kept in the range of about 0°C to about 60°C.

17. The process according to claim 6, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil having a purity greater than 98.5%, the E-isomer is less than 1.0% and the Δ^2-isomer impurity is less than 1%.

18. A process for preparing an amorphous form cefditoren pivoxil from crystalline cefditoren pivoxil, the process comprising:

a) dissolving crystalline cefditoren pivoxil in a first organic solvent;

b) adding a second organic solvent to the solution or adding the solution to the second organic solvent in optional order of succession to precipitate cefditoren pivoxil; and

c) isolating the amorphous cefditoren pivoxil from the reaction mixture.

19. The process according to claim 18, wherein the first organic solvent is at least one water-immiscible or partially miscible solvent.

20. The process according to claim 19, wherein the at least one water-immiscible or partially miscible solvent is an alcohol, a ketone, an ester, a chlorinated hydrocarbon or a mixture thereof.

21. The process according to claim 18, wherein the second organic solvent is an alkyl ether, a hydrocarbon or a mixture thereof.

22. The process according to claim 18, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the Δ^2-isomer impurity is less than 1%.

23. The process according to claim 18, wherein the dissolution of crystalline cefditoren pivoxil in the first organic solvent is effected by initially dissolving crystalline cefditoren pivoxil in a third organic solvent.

24. The process according to claim 23, wherein the third organic solvent is one or more of dimethylformamide, dimethylacetamide, tetrahydrofuran, 1,4-dioxane, methanol, acetone, acetonitrile, ethanol, isopropanol or a mixture thereof.

25. A process for preparing an amorphous form of cefditoren pivoxil, the process comprising the steps of:

a) dissolving crystalline cefditoren pivoxil in a first organic solvent;

b) removing the first organic solvent from the reaction mixture; and

c) isolating the amorphous form of cefditoren pivoxil.

26. The process according to claim 25, wherein the first organic solvent is at least one water-immiscible or partially miscible solvent.

27. The process according to claim 26, wherein the at least one water-immiscible or partially miscible solvent is an alcohol, a ketone, an ester, a chlorinated hydrocarbon or a mixture thereof.

28. The process according to claim 26, further comprising applying heat to dissolve the crystalline form in the first organic solvent.

29. The process according to claim 26, wherein the first organic solvent is removed under reduced pressure.

30. The process according to claim 26, wherein the first organic solvent is removed by spray-drying the solution of crystalline cefditoren pivoxil.

31. The process according to claim 25, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the Δ^2-isomer impurity is less than 1%.

32. A process for preparing a highly pure amorphous form of cefditoren pivoxil from crystalline form which comprises the steps of:

a) dissolving a crystalline form of cefditoren pivoxil in an organic solvent optionally containing water; and

b) freeze drying or lyophilizing the solution to get highly pure amorphous form of cefditoren pivoxil, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the Δ^2-isomer impurity is less than 1%.

33. The process according to claim 32, wherein the organic solvent comprises at least one water-immiscible or partially miscible solvent.

34. The process according to claim 33, wherein the at least one water-immiscible or partially miscible solvent is an alcohol, a ketone, an ester, a chlorinated hydrocarbon or a mixture thereof.

35. The process according to claim 32, further comprising applying heating to dissolve the crystalline form in the organic solvent.

36. A process for preparing a highly pure amorphous form of cefditoren pivoxil from crystalline form, the process comprising the steps of:

a) dissolving the crystalline cefditoren pivoxil in an acid, optionally in the presence of a water miscible organic solvent;

b) adding water to the solution in an amount sufficient to precipitate the cefditoren pivoxil from the solution; and

c) isolating the highly pure amorphous cefditoren pivoxil from the solution, wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a

purity greater than 98.5%, the E-isomer is less than 1.0% and the Δ^2-isomer impurity is less than 1%.

37. The process according to claim 36, wherein the acid is at least one of an organic acid or an inorganic acid.

38. The process according to claim 37, wherein the organic acid is one or more of C_{1-12} alkyl or aryl carboxylic acids, C_{1-10} alkyl or aryl sulphonic acids or a mixture thereof.

39. The process according to claim 38, wherein the C_{1-10} alkyl or aryl carboxylic acid is one or more of formic acid, acetic acid, propionic acid, butyric acid, acrylic acid, benzoic acid, mono-, di- or trisubstituted benzoic acids, phenyl acetic acid, substituted phenyl acetic acid or a mixture thereof.

40. The process according to claim 38, wherein the C_{1-12} alkyl or aryl sulphonic acid is one or more of methanesulphonic acid, p-toluenesulphonic acid, benzenesulphonic acid or a mixture thereof.

41. The process according to claim 37, wherein inorganic acid is one or more of hydrochloric acid, nitric acid, sulphuric acid, phosphoric acid or a mixture thereof.

42. The process according to claim 36, wherein the acid contains a water miscible organic solvent.

43. The process according to claim 42, wherein water miscible organic solvent is one or more of dimethylformamide, dimethylacetamide, tetrahydrofuran, 1,4-dioxane, methanol, acetone, acetonitrile, ethanol, isopropanol or a mixture thereof.

44. A process for converting a mixture of the amorphous and crystalline forms of cefditoren pivoxil to highly pure amorphous form of cefditoren pivoxil, wherein the mixture of amorphous and crystalline form of cefditoren pivoxil is prepared directly from the reaction mixture, from the crystalline form or from the amorphous form of cefditoren pivoxil and the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the Δ^2-isomer impurity is less than 1%.

45. A pharmaceutical composition comprising a highly pure amorphous or crystalline form of cefditoren pivoxil and a pharmaceutically acceptable carrier, wherein the cefditoren pivoxil is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the Δ^2-isomer impurity is less than 1%.

46. A method of treating infections caused by gram positive, gram negative and resistant strains of bacteria comprising administering to a mammalian host in need thereof a therapeutically effective amount of the highly pure amorphous or crystalline form of cefditoren pivoxil, wherein the cefditoren pivoxil is highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than 1.0% and the Δ^2-isomer impurity is less than 1%.